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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,717	08/22/2001	Masahiro Imoto	1830/50325	6281

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

<b>Application No.</b> 09/933,717	<b>Applicant(s)</b> IMOTO ET AL.	
<b>Examiner</b> Brenda L. Coleman	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 04 April 2005.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1,4,8,10,13,17,18 and 25-29 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1,4,8,10,13,17,18 and 25-29 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \*    c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1, 4, 8, 10, 13, 17, 18 and 25-29 are pending in the application.

This action is in response to applicant's amendment filed April 4, 2005. Claims 1, 4 and 18 have been amended.

#### ***Response to Amendment***

Applicant's arguments filed April 4, 2005 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1, 4, 8, 10, 13 and 17-29, labeled paragraph 3) in the last office action. The applicants' remarks and declaration from Dr. Yoshihiro Tani concerning the enablement of claims 1, 4, 8, 19, 13 and 17-29 are such that in view of the combined teachings of the specification and the knowledge of one skilled in the art have been fully considered but were not found persuasive. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims where the disorder is treatable with a nicotinic acetylcholine receptor ligand. As stated in the last office action it is difficult to treat many of the disorders claimed herein. Recent studies on experimental and clinical pharmacology of nicotinic acetylcholine receptors cited in Annual Reports in Medicinal Chemistry indicate that the following disorders may be associated with nicotinic acetylcholine receptors: senile dementia of the Alzheimer's type, Parkinson's disease, Huntington's chorea, tardive dyskinesia, hyperkinesia, mania, depression, attention deficit disorder, anxiety, dyslexia, schizophrenia, Tourette's syndrome and smoking cessation. The "nicotinic"

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effect with respect to Alzheimer's is hypothesized. Parkinson's Disease is "presently of unknown etiology" and recent studies have exhibited dosing problems as well as "unusually high placebo effects". The pathophysiology of Tourette's syndrome is unknown. The treatment of ulcerative colitis is currently "limited to anti-inflammatories, immunosuppressants and antibiotics". Additionally, there are other pathological non-CNS conditions, such as pouchitis and influenza virus-induced pneumonitis, where nicotine efficacy has been reported, but remains to be confirmed.

It is difficult to treat many of the disorders claimed herein. Instant claim language embraces disorders not only for treatment but for the prevention or prophylactics, which is not remotely enabled. It is presumed in the prevention of the diseases and/or disorders claimed herein there is a way of identifying those people who may develop osteoporosis, etc. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders claimed herein.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221; *Ex parte Jovanovics*, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001.

Claims 1, 4, 8, 10, 13, 17, 18 and 25-29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 1, 4, 8 and 19-29, labeled paragraph 4 in the last office action, which is hereby **withdrawn**.

3. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, second paragraph rejection labeled paragraph 5a), b) and c) of the last office action, which is hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled d) the applicant's amendments and remarks have been fully considered but they are not persuasive.

d) The applicants' stated that the claims 8, 17 and 25-29 are directed to methods and that claim 8 and 17 are directed to methods of activating  $\alpha 4\beta 2$  nicotinic acetylcholine receptors and do not recite treating, inhibiting or otherwise preventing any particular disease or disorder. However, claims 8 and 17 generically claims the method of treating a disorder responsive to the activity of nAChR modulators. The rejection of claims 8 and 17 was on the grounds that it is indefinite, in that it is not known which diseases are capable of being responsive to the activity of nAChR modulators. The scope of diseases and/or

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disorders associated with the activity of nAChR modulators could alter over time. The applicants' are not entitled to preempt the efforts of others. The applicants also stated that the claims are directed to the physiological effect the compounds have on biological systems (activating  $\alpha 4\beta 2$  nicotinic acetylcholine receptors). However, it is not known what biological system or physiological effect this pertains, that is the applicants have not set forth the metes and bounds of the claim.

Claims 1, 4, 8, 10, 13, 17, 18 and 25-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

4. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 102, anticipation rejection of claims 1, 4, 10 and 18, labeled paragraph 6 in the last office action, which is hereby **withdrawn**.

5. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 102, anticipation rejection of claims 1, 4, 10 and 19-22, labeled paragraph 7 in the last office action, which is hereby **withdrawn**.

6. With regards to the 35 USC § 102, anticipation rejection of claim 1, labeled paragraph 8 in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicants stated that claims 1 has been amended to delete the reference to "halogen", "nitro" and "cyano" in the

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definition of A, as well as "pyridine" and "thiazole". The applicants' also stated that Brown does not appear to provide the methyl bridge which attaches the A group as claim. However, the species of Brown anticipated herein is 1-benzyl-1,2-dihydro-2-iminopyrimidine in line 4 of the second column on page 908.

7. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 102, anticipation rejection of claim 1, labeled paragraph 9 in the last office action, which is hereby **withdrawn**.

8. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 102, anticipation rejection of claim 1, labeled paragraph 10 in the last office action, which is hereby **withdrawn**.

In view of the amendment dated April 4, 2005, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 4, 8, 10, 13, 17 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The definition of R<sup>8</sup>

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and R<sup>9</sup> where R<sup>8</sup> and R<sup>9</sup> are C<sub>1</sub>-C<sub>4</sub> alkyl group is not described in the specification with respect to the genus.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1, 4, 8, 10, 13 and 17-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claim 1 is vague and indefinite in that it is not known what is meant by the open parenthesis in the definition of -Y-X- of which there is no close parenthesis.

### **Conclusion**

11. Applicants' attention is directed to U.S. Patent No. 6,303,638, which while not competent as a reference against the instant claims in view of the applicants' filing of a certified translation of their priority document, claims subject matter that is similar and/or identical to that claimed herein. Two patents cannot issue on the same subject matter, unless applicants can demonstrate that the claims are patentably distinct from the claims of this US patent, the only way to overcome this patent is by way of Interference proceedings or removal of the conflicting subject matter. See MPEP 2306.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Brenda Coleman  
Primary Examiner Art Unit 1624  
June 16, 2005